

Your Product

Quick to Tox

Quick to Clinic

# GMP VHH Technology Platform

**From cell bank to GMP material in 8 months**

With over **40 years of experience** in **recombinant protein** expression, we've developed a **robust microbial platform** dedicated to the **rapid and reliable production of VHH antibodies** in *E. coli* or *P. pastoris* (*K. phaffii*), with **scalable** output and full **GMP** compliance.



From RCB to clinic in  
only **8 months**



End-to-End  
**Assistance**



**GMP** Quality



Designed for  
**Tox & Ph I**

# VHH platform for optimized production

We've built a **robust VHH production platform**, developed through **extensive testing** on a diverse set of VHH models, including:

- | **Mono-, bi-, and tri-specific** formats
- | **Isoelectric points between pI 5 and 9**
- | **Diverse hydrophobicity** properties

This toolbox allows us to **rapidly assess your VHH product against our optimized fermentation and purification platform**, enabling the fast delivery of high-quality material suitable for **Tox studies** and **Phase I** human clinical trials.

**The toolbox** integrates various **microbial host systems, fermentation strategies, purification, and QC methods** to rapidly fine-tune each production process.



## Two expression platforms

– ***P. pastoris (K. phaffii)***  
High-density yeast system for secreted, endotoxin-free VHH production. Enables easier purification and scalable, cost-efficient manufacturing.

– ***E. coli***  
Well-characterized bacterial system, for simpler VHH formats progressing toward clinical trials.

## Fermentation

- High-cell density fed-batch
- Control of critical fermentation parameters
- Animal-free media

## Purification

- Ion-Exchange
- Hydrophobic Interaction Chromatography (HIC)
- Mix mode
- Affinity

## Quality Control & Release

- GMP QC package
- Additional custom QC development available
- QP release

## Support

- Project Management
- Dedicated team
- VHH Experts
- Tailored made solution

# Accelerate time to clinic

## Fast track to purified VHH

Starting from your research cell bank, we **rapidly identify** the most suitable **fermentation** and **purification** conditions for your VHH molecule. This ensures the fast delivery of **purified material**, optimized for **Tox studies** and **Phase I** clinical trials and GMP readiness.

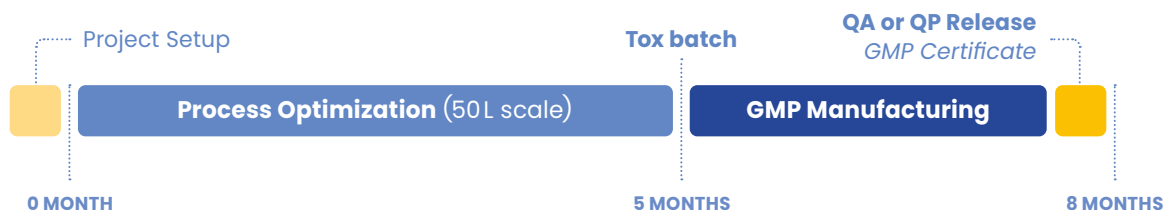


## Reduced time to commercialization

With **scalable microbial processes** and **GMP-compliant** production capabilities, our VHH platform and CDMO expertise support your project through **preclinical**, **clinical**, and **commercial** stages, **accelerating the path to market** for your VHH-based drug substance. We also offer the possibility to validate your process for future commercial phases.

## Timeline for GMP-Grade VHH Manufacturing

From Feasibility to Clinical Supply



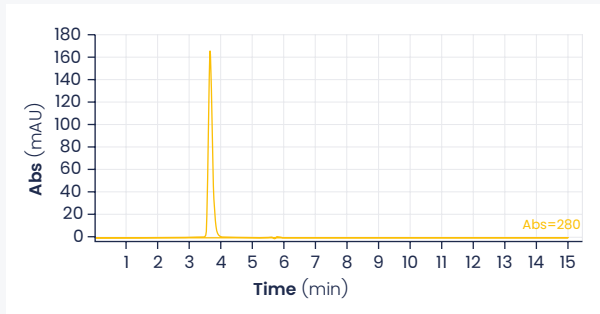
## GMP QC package

Our GMP QC package includes a full panel of analytical methods for GMP-grade VHH release. Optional tests can be added based on your molecule's specific needs.

Attributes	Testing
<b>Identity</b>	SDS-PAGE SE-HPLC
<b>Purity</b>	Molecular size distribution by SE-HPLC UV-spectrometry
<b>Protein content</b>	UV / $\mu$ BCA / Lowry
<b>Impurity</b>	Host Cell Protein by ELISA Host Cell DNA by qPCR
<b>Safety</b>	Endotoxin Bioburden
<b>Residual</b>	Methanol / IPTG Protein A (ELISA)
<b>Appearance</b>	Colorimetry Turbidimetry

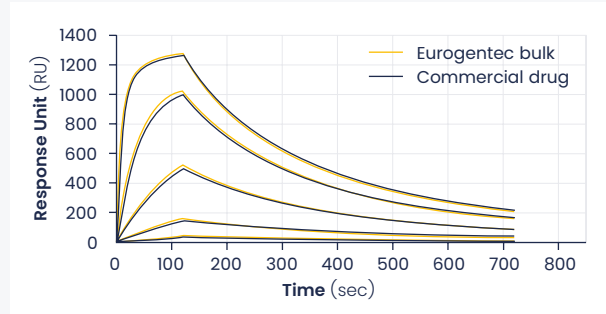
Attributes	Testing
<b>Physico-chemical</b>	pH
<b>Additional QCs</b>	
<b>Identity</b>	ESI-Q-TOF RP-HPLC Western blotting
<b>Purity</b>	RP-HPLC
<b>Physico-chemical</b>	Visible particles Osmolarity
<b>Potency</b>	Antigen binding assay by SPR ELISA

# High quality



## High Purity level

SE-HPLC analysis of a **trivalent bispecific VHH** shows a purity level of **98.7%**.



## Binding affinity testing

SPR analysis (Biacore system) confirms that Eurogentec's bulk material displays **binding affinity equivalent to the commercial reference**, with Kd values of 19.7 nM and 20.9 nM, respectively.



## Dedicated Support

We offer **personalized support**, **transparent communication**, and **tailored solutions** to meet your technical and regulatory needs. Our **dedicated project managers** and experienced **VHH specialists** guide you from early development to GMP release.

### Contact us

For more information or to discuss your VHH project, feel free to reach out.



Scan and write us at  
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